IP-37-001-0902

Information Paper

Shipping ThinPrep® Solutions and Samples within CONUS

April 2003

1. Background. Department of Defense (DOD) medical facilities collect and process specimens for testing for cervical cancer using the ThinPrep® PreservCyt® solution made by the Cytyc Corporation. PreservCyt® is a methanol-based, buffered preservative solution and is classified as a hazardous material (HM) due to its low flashpoint (80°F/26.5°C). Packaging and transport processes for ThinPrep® virgin collection vials and collected specimens are determined by the flammability characteristic. Each vial contains 20mL of PreservCyt® solution. *This information paper is intended primarily for use by personnel who have successfully completed a hazardous materials shipping course, such as the USACHPPM's Transport of Biomedical Material course.*

2. Training. Personnel who package and ship ThinPrep® solutions and samples must minimally receive general awareness, function specific, and safety training. This training is conducted at a supervisory level and required within 90 days of employment per 49 CFR 172.704 and International Air Transport Association (IATA) Regulations Chapter 1, Section 1.5. All personnel who sign hazardous materials **shipping papers** for ThinPrep® shipments must be formally trained per Defense Transportation Regulations, DOD Regulation 4500.9-R, Part II, Chapter 204, Section D (http://www.transcom.mil/J4/j4lt/dtr.html). Specialized training certification can be obtained by successfully completing the Transport of Biomedical Material Course given by the U.S. Army Center for Health Promotion and Preventive Medicine. Registration for the Transport of Biomedical Material Course is available at http://chppm-www.apgea.army.mil/trng. As stated above, this information paper does not preclude the requirement for specialized training at an approved course for personnel signing hazardous materials shipping papers.

3. Hazard Classification. There is no known reason to suspect that these diagnostic specimens contain a pathogen and therefore are not restricted for shipment as defined in 49 CFR 173.134 and IATA Chapter 3, Section 3.6.2. The flammability of the PreservCyt® solution is the hazard that must be addressed for transport. Based on the manufacturer's Material Safety Data Sheet (http://www.cytyc.com/pdffiles/85093002G.pdf), the proper basic description with technical name for new material or collected specimens is: Flammable Liquids, n.o.s. (contains methanol), 3, UN1993, III.

4. Determine the type of shipment and mode of transport: **The total amount of vials to be shipped will determine whether the vials/specimens qualify for transport as a small**

quantity exception, a limited quantity, or non-bulk shipment. A small quantity exception, called an "excepted quantity," is a very small amount of HM that presents minimal risks to human health, property, and the environment during transport. If the quantity of vials to be shipped exceeds the limits for transport as an excepted quantity, the package may qualify as a limited quantity shipment. If the quantity exceeds both the excepted and limited quantity limits, it meets the definition of a non-bulk shipment. The following table is a guide based on quantity being shipped.

Number of 20 mL Vials per outer packaging	Shipping Method	Note	Information Paper Reference Paragraph
≤ 50	Excepted Quantity	Weight limit is 29 kg/64 lbs.	Highway or commercial air - 4.a.
≥ 50 but ≤ 500	Limited Quantity	Weight limit is 30 kg/66 lbs. Check mode of transport for further information.	Highway - 4.b.i. Commercial Air - 4.b.ii.
≥ 500	Non-bulk Shipment	Weight limit is 400 kg/882 lbs.	Highway - 4.c.i. Commercial Air - 4.c.ii.

a. Excepted Quantity (highway or commercial air): New vials of PreservCyt® solution or specimens collected in PreservCyt® may be shipped as an excepted quantity as defined in 49 CFR Part 173.4 and in the IATA, Chapter 2, Section 2.7 **provided** each inner receptacle (vial) does not contain more than 30mL of solution and the total outer package does not contain more than 1000mL (1L) of HM. [A maximum of 50 of the 20mL vials may be shipped in one package as an excepted quantity as long as the total outer packaging weight does not exceed 29 kg (64 pounds).] Excepted quantities of certain HM classes may be exempt from some marking, labeling, and shipping paper requirements when transported.

i. Packaging: Each inner receptacle with a removable closure must be secured with wire, tape, or some other positive means to prevent leakage. The inner receptacles must be securely packed in cushioning material. Sufficient, compatible (non-reactive) absorbent material must be used to absorb the entire contents of the inner receptacles in case of leakage. Outer packagings must meet UN performance specifications for **Packing Group I**. [Note the packing group (per 49 CFR 173.4 and 178.603 and IATA 2.7).] The size of the outer packaging must be equal to or more than 100mm by 100mm per IATA 2.7.8.9. The weight of the completed outer package cannot exceed 29 kg (64 pounds) per 49 CFR 173.4(a)(8).

ii. Marking and Labeling: By ground transport (highway), the outer package must be marked with the statement "This package conforms to 49 CFR 173.4." If shipped by commercial air, a Dangerous Goods in Excepted Quantities label must be completed and placed on the outer packaging. (IATA 2.7.6, Figure 2.7B).

iii. Shipping Papers: If the shipment is to be transported by government courier over public highways to/from the outlying clinic, a hazardous material shipping paper is not

required. By commercial ground transport, a bill of lading may be used to document the shipment. However, no hazardous materials shipping papers or placards are required for transport by commercial ground transport. Transport by commercial air requires that the "Nature and Quantity of Goods" box on the airway bill be marked with the statement "Dangerous Goods in Excepted Quantities." No shipper's declaration for dangerous goods is required for commercial air transport.

b. Limited Quantity: Limited quantity requirements are defined in 49 CFR 172.101, column 8A and IATA Regulations, Chapter 2, Section 2.8. New vials of PreservCyt® solution or specimens collected in PreservCyt® may be shipped as a limited quantity **provided** each inner receptacle (vial) does not contain more than 5L of solution. Since the PreservCyt® is pre-packaged in 20mL vials, the inner receptacle limit of 5L is an unlikely occurrence. However, there are limits on the total quantity that can be shipped per outer package. Determine the mode of transport – highway or commercial air.

i. Highway: The 49 CFR 172.101, Hazardous Materials Table, Column 8A (Exceptions) directs you to the appropriate section under 49 CFR Part 173 that determines the quantity limits and types of packaging that can be used to ship that particular HM. The proper shipping name "Flammable Liquids, n.o.s.," lists three packing groups. Based on the information provided in paragraph 3 above, select Column 8A for Packing Group III, which directs you to 49 CFR 173.150.

(1) Packaging: Each inner receptacle with a removable closure must be secured with wire, tape, or some other positive means to prevent leakage. The inner receptacles must be securely packed in cushioning material. Sufficient, compatible (non-reactive) absorbent material must be used to absorb the entire contents of the inner receptacles in case of leakage. Strong outer packagings that are able to withstand the rigors of transport must be used (49 CFR 173.150(b)(3), 171.8, 173.24, 173.24a). Under 49 CFR 173.150(b), you may ship PreservCyt® solution or specimens as a limited quantity as long as the weight of the completed outer packaging does not exceed 30 kg (66 pounds). In this case, the number of vials is not the limiting factor but the overall package weight.

(2) Marking and Labeling. The proper shipping name with the technical name [Flammable Liquid, n.o.s., (contains methanol)] must be marked on the outer packaging near the receiver's name and address. Hazard labels and the UN ID number are not required.

(3) Shipping Papers: If the shipment is to be transported by government courier over public highways to/from the outlying clinics, use a DD836, Dangerous Good Shipping Paper as the hazardous material shipping paper. Complete in accordance with the instructions found in the DOD 4500.9-R, Part II, Chapter 204. A bill of lading may be used to document the commercial ground transport (highway) shipment. Complete the hazardous material shipping paper as outlined in 49 CFR 172.200 through 172.205 and put the words "Limited Quantity" after the basic description [49 CFR 172.203(b)]. No emergency response number is required on the shipping paper [49 CFR 172.604(c)(1)]. No placards are required.

ii. Commercial air: New vials of PreservCyt® solution or specimens collected in PreservCyt® may be shipped as a limited quantity as defined in the IATA Regulations, Chapter 2, Section 2.8. Chapter 4 of the IATA, the Dangerous Goods List, directs you to the proper packing instruction to determine the quantity limits and types of packaging that can be used to ship PreservCyt®. For new vials of PreservCyt® solution or specimens collected in PreservCyt®, use the basic description with technical name as described in paragraph 3 above.

(1) Packaging: Flammable liquids, n.o.s., Packing Group III, directs you to Packing Instruction Y309 for limited quantity shipments. Each inner receptacle with a removable closure must be secured with wire, tape, or some other positive means to prevent leakage. The inner receptacles must be securely packed in cushioning material. Sufficient, compatible (non-reactive) absorbent material must be used to absorb the entire contents of the inner receptacles in case of leakage. Outer packagings must meet UN performance specifications for **Packing Group II**. (Note the packing group, per IATA 2.8.5.) Under IATA Section 2.8.4, you may ship PreservCyt® solution or specimens as a limited quantity as long as the total outer packaging weight does not exceed 30 kg (66 pounds). The maximum quantity permitted in one outer packaging is 10,000 mL (10L). [A maximum of 500 each 20mL vials may be shipped in one package as a limited quantity as long as the weight of the completed outer packaging does not exceed 30 kg (66 pounds).]

(2) Marking and Labeling: Mark the proper shipping name (with technical name), UN ID number and "LTD QTY" [Flammable Liquid, n.o.s., (contains methanol), UN 1993, LTD QTY] on the outer packaging near the receiver's full name and address (IATA Section 7.1.5). Mark the shipper's full name and address on the outer packaging. Mark package orientation markings on at least two opposite sides of the outer packaging. Labeling is required. Affix Flammable Liquid (Hazard Class 3) label to the outer packaging on the same surface as the proper shipping name, near the receiver's address. [Yes, both the shipper's and receiver's full names and addresses must be marked on the outer package when shipping by commercial air.]

(3) Shipping Papers: A shipper's declaration for dangerous goods and an airway bill are required. Complete the shipper's declaration for dangerous goods according the instructions found in IATA Chapter 8, Section 8.1.6. Complete the airway bill per the carrier's instructions.

c. Non-bulk shipment. If the ThinPrep® vials or samples cannot be shipped as an excepted or limited quantity, then transport as a non-bulk shipment is required. The definition of non-bulk packaging can be found in 49 CFR 171.8.

i. Highway: The 49 CFR 172.101, Hazardous Materials Table, Column 8B (Non-bulk) directs you to the appropriate section under 49 CFR Part 173 that determines the quantity limits and types of packaging that can be used to ship that particular HM. The proper shipping name "Flammable Liquids, n.o.s.," lists three packing groups. Based on the information provided in paragraph 3 above, select Packing Group III, which directs you to 49 CFR 173.203.

(1) Packaging: Each inner receptacle with a removable closure must be secured with wire, tape, or some other positive means to prevent leakage. The inner receptacles must be

securely packed in cushioning material. Sufficient, compatible (non-reactive) absorbent material must be used to absorb the entire contents of the inner receptacles in case of leakage. Outer packagings must meet UN performance specifications for **Packing Group III**. (Note the packing group.) Under 49 CFR 173.203, you may ship PreservCyt® solution or specimens as a non-bulk package as long as the total outer packaging weight does not exceed 400 kg (882 pounds).

(2) Marking, Labeling, and Placarding: Mark the proper shipping name (with technical name) and UN ID number [Flammable Liquid, n.o.s., (contains methanol), UN 1993] on the outer packaging near the receiver's full name and address. Mark the receiver's full name and address on the outer packaging. Mark package orientation markings on at least two opposite sides of the outer packaging. Labeling is required. Affix Flammable Liquid (Hazard Class 3) label to the outer packaging on the same surface as the proper shipping name, near the receiver's address. Placarding may be required. Consult 49 CFR 172.500-506 for further information about placarding.

(3) Shipping Papers: If the shipment is to be transported by government courier over public highways to/from the outlying clinics, use a DD836, Dangerous Good Shipping Paper, as the hazardous material shipping paper. Complete in accordance with the instructions found in the DOD 4500.9-R, Part II, Chapter 204. A bill of lading may be used to document commercial ground transport shipment. Complete the hazardous material shipping paper as outlined in 49 CFR 172.200 through 172.205.

ii. Commercial air: New vials of PreservCyt® solution or specimens collected in PreservCyt® may be shipped on passenger or cargo aircraft based on the total quantity per inner and/or outer package. IATA Regulations, Chapter 4, the Dangerous Goods List, directs you to the proper packing instruction to determine the quantity limits and type of packaging that can be used to ship PreservCyt®. For new vials of PreservCyt® solution or specimens collected in PreservCyt®, use the basic description with technical name as described in paragraph 3 above.

(1) Packaging: Flammable liquids, n.o.s., Packing Group III, directs you to Packing Instruction 309 for passenger and cargo aircraft shipments. Each inner receptacle with a removable closure must be secured with wire, tape, or some other positive means to prevent leakage. The inner receptacles must be securely packed in cushioning material. Sufficient, compatible (non-reactive) absorbent material must be used to absorb the entire contents of the inner receptacles. Outer packagings must meet UN performance specifications for **Packing Group III**. The maximum quantity per inner packaging is 10,000mL (10L). Since the PreservCyt® is pre-packaged in 20mL vials, the inner receptacle limit of 10L is an unlikely occurrence. The maximum quantity permitted in one outer packaging is 60,000 mL (60L). [A maximum of 3,000 each 20mL vials may be shipped in each non-bulk combination packaging.]

(2) Marking and Labeling: Mark the proper shipping name (with technical name) and UN ID number [Flammable Liquid, n.o.s., (contains methanol), UN 1993] on the outer packaging near the receiver's full name and address. Mark the shipper's and receiver's full name and address on the outer packaging. Mark package orientation markings on at least two opposite sides of the outer packaging. Labeling is required. Affix Flammable Liquid (Hazard

Class 3) label to the outer packaging on the same surface as the proper shipping name, near the receiver's address. A Cargo Aircraft Only label may be required (IATA 7.2.4.2).

(3) Shipping Papers: A shipper's declaration for dangerous goods and an airway bill are required. Complete the shipper's declaration for dangerous goods according the instructions found in IATA Chapter 8, Section 8.1.6. Complete the airway bill per the carrier's instructions.

5. For waste management issues, procedures and regulatory requirements, see USACHPPM Fact Sheet, Management of Waste from the ThinPrep® Processor, http://chppm-www.apgea.army.mil/hmwp/ then Facts Sheets, Hazardous Waste.

Hazardous and Medical Waste Program, Ms. Vicki Strause
U.S. Army Center for Health Promotion and Preventive Medicine
5158 Blackhawk Road
Aberdeen Proving Ground, MD 21010-5403
DSN 584-3651 or Commercial 410-436-3651

Back to Fact Sheet Index